THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

KELLY LINKENMEYER, Plaintiff, v. NOVARTIS PHARMACEUTICALS, CORPORATION, NOVARTIS PHARMA GMBH, and NOVARTIS AG, Defendants.	HON. JEROME B. SIMANDLE Civil No. 07-1657 (JBS) **MEMORANDUM OPINION**
VICTORIA ANDERSON, Plaintiff, v. NOVARTIS PHARMACEUTICALS, CORPORATION, NOVARTIS PHARMA GMBH, and NOVARTIS AG, Defendants.	Civil No. 07-2774 (JBS)

SIMANDLE, District Judge:

This matter is before the Court on the motions of Plaintiffs Kelly Linkenmeyer and Victoria Anderson to remand their cases to the Superior Court of New Jersey, Atlantic County, where the cases were originally filed [Docket Items 15 and 7]. THIS COURT FINDS AS FOLLOWS:

1. Plaintiffs Linkenmeyer and Anderson filed these two actions against defendants Novartis Pharmaceuticals Corporation, Novartis Pharma GMBH, and Novartis AG ("Novartis") in the Superior Court of New Jersey, seeking damages for injuries that

both women allegedly sustained as a result of using Defendant's eczema drug, Elidel. Plaintiffs both claim that they contracted cancer through the use of Elidel, and each alleges, among other claims, that her injuries were the result of Novartis' failure to provide adequate warnings regarding the risks associated with its product.

2. On April 9, 2007 and June 13, 2007, Novartis filed a notice of removal to this Court in each plaintiff's lawsuit pursuant to 28 U.S.C. § 1331 [Docket Item 1], arguing in both cases that the plaintiffs' lawsuits raise federal questions regarding, inter alia, whether product liability claims based on state tort law are preempted by Food and Drug Administration ("FDA") regulations governing the labeling of pharmaceuticals. Plaintiffs each moved to remand their cases to the Superior Court of New Jersey, arguing that the cases were improperly removed to this Court because their claims did not involve sufficiently weighty questions of federal law to trigger federal question jurisdiction.

3. For the following reasons, the Court will temporarily stay all proceedings in both of these matters pending the decision of the Court of Appeals for the Third Circuit in McNellis v. Pfizer, Inc., Docket No. 06-5148, and Colacicco v. Apotex, Inc., Docket No. 06-3107, two related cases that raise issues concerning the preemptive force of the FDA's labeling

regulations that are potentially dispositive to the present cases.

4. It is well-settled that "[i]n the exercise of its sound discretion, a court may hold one lawsuit in abeyance to abide the outcome of another which may substantially affect it or be dispositive of the issues." Bechtel Corp. v. Local 215, Laborers' Intern. Union of North America, 544 F.2d 1207, 1215 (3d Cir. 1976). As the Supreme Court stated in Landis v. North American Co., 299 U.S. 248, 254 (1936), "the power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." Among the factors that courts take into account when assessing the suitability of issuing a stay are "whether a stay will simplify issues and promote judicial economy, the balance of harm to the parties, and the length of the [] stay." Glades Pharmaceuticals, LLC v. Call, Inc., No. Civ. A. 04-4259, 2005 WL 563726, at *8 (E.D.Pa. Mar. 9, 2005) (internal quotations omitted).

5. Weighing the parties' interests, the length of the potential stay, and, most critically in this case, the strong likelihood that the forthcoming decision of the Court of Appeals will have potentially dispositive implications for a central issue in each of these disputes, the Court has determined that it

is appropriate to stay these cases pending the decision of the Court of Appeals in McNellis and Colacicco.

6. At the heart of both lawsuits is the question of whether state tort law product liability claims are preempted by FDA regulations governing drug labels. Plaintiffs' cases are premised in part on the argument that the alleged failure by Novartis to warn of known risks associated with Elidel is actionable under New Jersey law. Novartis argues that Plaintiffs' claims "impermissibly conflict with FDA regulatory determinations under the Federal Food, Drug, and Cosmetic Act" ("FCDA") and are therefore preempted by federal law. (Def.'s Br. 1.)

7. The preemptive effect of the FDA's pharmaceutical labeling regulations is an issue that has divided the courts in the Third Circuit. In McNellis ex rel. DeAngelis v. Pfizer, Inc. ("McNellis I"), this Court held that the FDA's regulations regarding pharmaceutical labeling requirements do not conflict with state tort laws that impose liability for a manufacturer's failure to warn of known risks associated with its product because the FDA's regulations "merely set minimum standards with which manufacturers must comply." No. 05-1286, 2005 WL 3752269, at *7 (D.N.J. Dec. 29, 2005). The Court reasoned that a finding that the regulations preempted state law in circumstances such as these would run afoul of "Congress' primary goal in enacting the

FDCA, which is to protect consumers from dangerous products, as well as Congress' stated intent that the FDCA must not weaken the existing laws, but on the contrary it must strengthen and extend that law's protection of the consumer." Id. (internal quotations and citations omitted).

8. The Court subsequently denied Pfizer's motion to vacate its December 29 Order. See McNellis ex rel DeAngelis v. Pfizer, Inc., No. 05-1286, 2006 WL 2819046 (D.N.J. Sept. 29, 2006) ("McNellis II"). The Court rejected Pfizer's argument that the preamble to a newly published FDA document called "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products" undermined the Court's December 29 Order. The Court found that the new preamble conflicted with the contents of the document itself, and that the preamble lacked the force of the regulations because it had not been subject to prior notice or comment, and because the preamble purported to reverse the FDA's longstanding policy of the non-preemption of state laws regarding the adequacy of warning where, as here, the state law requirements can be harmonized with the manufacturers' labeling duties under the FDCA, and because enforcing the preamble would nullify the very regulations it purported to interpret. Id. at *6-7. The Court did, however, grant Pfizer's motion to certify the Court's two Orders for interlocutory appeal so that the Court

of Appeals could address the contested preemption questions at issue in the case.

9. In addressing the same question of preemption that this Court addressed in McNellis, the court in Colacicco v. Apotex, Inc., 432 F. Supp. 2d 514 (E.D. Pa. 2006), reached a different conclusion, finding that the FDCA preempted Pennsylvania's failure-to-warn claims. In Colacicco, the court adopted the argument, rejected by this Court in McNellis II, that "principles of deference do not allow [the court] to question the FDA's interpretation of its own regulations." Id. at 528.

10. McNellis and Colacicco thus each addressed one of the central issues in the cases presently under consideration – whether the FDA's pharmaceutical labeling regulations preempt state failure-to-warn laws – and arrived at inconsistent conclusions. With both of those cases pending before the Court of Appeals, it is all but certain that a forthcoming decision by that court will "be dispositive of [some of] the issues" in both Ms. Linkenmeyer's and Ms. Anderson's cases, indicating that an order staying both cases is appropriate. Bechtel Corp., 544 F.2d at 1215.

11. The Court's decision to stay these cases is further supported by the brevity of the delay that the parties would experience in awaiting the decision of the Court of Appeals. See Glades Pharmaceuticals, No. Civ. A. 04-4259, 2005 WL 563726, at

*8. The Court of Appeals heard oral argument on McNellis and Colacicco on December 10, 2007. This is, therefore, not a case where the contemplated stay is open-ended or protracted – the Court of Appeals will very shortly have the opportunity to clarify the disputed question of conflict preemption that is at the heart of this case. Such a brief stay carries little risk that any party's interests in these cases will be seriously harmed pending the decision of the Court of Appeals, and whatever minimal inconvenience the parties experience as a result of the stay is, in the Court's mind, clearly acceptable when balanced against the likelihood that the decision of Court of Appeals will resolve a legal issue with potentially dispositive implications for these cases.

CONCLUSION

For the foregoing reasons, the Court will temporarily stay all proceedings in these cases pending the decision of the Court of Appeals in McNellis and Colacicco.

March 10, 2008
DATE

s/ Jerome B. Simandle
JEROME B. SIMANDLE
U.S. District Judge